# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

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Plaintiff,

Civil Action No.

v.

BIOCON LTD. AND BICARA THERAPEUTICS, INC.,

JURY TRIAL DEMANDED

Defendants.

### **COMPLAINT**

Plaintiff Y-Trap, Inc. ("Y-Trap" or "Plaintiff"), by its undersigned counsel, files this Complaint against Defendants Biocon Ltd. ("Biocon"), and Bicara Therapeutics, Inc. ("Bicara") (Biocon and Bicara jointly referred to as "Defendants"), and hereby allege, upon knowledge with respect to its own acts and upon information and belief as to all other matters, as follows:

#### PRELIMINARY STATEMENT

- 1. Y-Trap is a start-up biotechnology company, based in South San Francisco, in the business of researching and developing immunotherapy products to treat cancer, specifically, novel fusion proteins that counteract immune dysfunction in the tumor microenvironment.
- 2. Y-Trap is the exclusive licensee of a patent family co-invented by its co-founders Dr. Atul Bedi and Dr. Rajani Ravi, who assigned their inventions to the Johns Hopkins University ("JHU") (collectively, the "Bedi Intellectual Property"), including a patent family represented by PCT/US2011/027317 (the "'789 Bedi IP¹").

<sup>&</sup>lt;sup>1</sup> The '789 Bedi IP includes PCT/US2011/027317, which published as WO 2011/109789, and all related patents and foreign counterparts, including, but not limited to U.S. Patent Nos. 8,993,524; 9,441,044; 9,850,306; 10,442,860; and 11,274,156; Indian Patent Application 8417/CHENP/2012; and Indian Patent Nos. 481076 and 547495.

- 3. In the course of National Institutes of Health (NIH)-sponsored research at JHU, Drs. Bedi and Ravi made groundbreaking discoveries leading to the invention of a novel class of revolutionary molecules for cancer immunotherapy. This invention resulted from years of dedicated research aimed at understanding how cancers evade elimination by the immune system—a phenomenon known as "immune tolerance." To overcome this challenge, they invented a family of bifunctional antibody-ligand traps, known as Y-traps, designed to restore the ability of the immune system to attack cancer cells. These fusion proteins hold immense potential to offer life-saving clinical benefits for patients with cancer.
- 4. Central to this case, the '789 Bedi IP describes fusion proteins comprising a targeting antibody fused to an immunomodulatory moiety that binds and disables specific immunosuppressive ligands (for example, transforming growth factor-beta (TGF-β)). Specifically, the invention describes exemplary fusion proteins comprising a targeting antibody that binds epidermal growth factor receptor (EGFR) fused to an immunomodulatory moiety that is a ligand-binding sequence of the extracellular domain of TGFβRII. This fusion protein, hereafter referred to as "EGFR/TGFβ-binding fusion protein," promotes antitumor immunity by targeting EGFR-expressing tumor cells and simultaneously counteracting TGF-β-induced immune tolerance within the tumor microenvironment. Claims covering these fusion proteins have issued in multiple jurisdictions, including the U.S., Israel, and Japan.
- 5. Biocon, an Indian pharmaceutical company founded by its chairperson, Kiran Mazumdar-Shaw, received confidential information from Dr. Bedi in June 2010, following Dr. Bedi and Dr. Ravi's patent application filing. Under a confidential disclosure agreement ("CDA"), Dr. Bedi shared specific molecules from his patent application with Mazumdar-Shaw and Biocon, including fusion proteins consisting of an anti-EGFR antibody fused to the ligand-

binding sequence of the extracellular domain of TGFβRII. Mazumdar-Shaw and other Biocon employees were fully aware that these molecules were invented by Drs. Bedi and Ravi, who had already filed corresponding patent applications.

- 6. From June 2010 to April 2012, Mazumdar-Shaw and Biocon did not raise any claim of inventorship. Instead, during this period, Mazumdar-Shaw repeatedly pressured Dr. Bedi to help Biocon obtain a license to the '789 Bedi IP from JHU. In April 2012, Biocon abruptly changed course and filed its own copy-cat version of the '789 Bedi IP, falsely claiming inventorship of identical subject matter. For example, Biocon filed WO 2013/164694 and family members, collectively, the "Copycat Biocon IP<sup>2</sup>". This copied patent claims the same fusion proteins disclosed by Dr. Bedi to Biocon under the CDA, including the anti-EGFR antibody fused to a ligand-binding sequence of the extracellular domain of TGFβRII from the '789 Bedi IP. Biocon fraudulently listed its scientists as the inventors of the Copycat Biocon IP, despite knowing that Drs. Bedi and Ravi were its only rightful inventors.
- 7. Biocon concealed its plans to develop an EGFR/TGF-β-binding fusion protein until 2021, when it launched Bicara with \$40 million in seed money to develop and commercialize BCA101 (ficerafusp alfa). Mazumdar-Shaw appointed her niece, Claire Mazumdar, as CEO of Bicara to lead the effort. Bicara was created in order to usurp and monetize the '789 Bedi IP. BCA101 is a fusion protein copied from the '789 Bedi IP, comprising an anti-EGFR antibody fused to a ligand-binding extracellular domain of TGFβRII. BCA101 comprises the identical anti-EGFR antibody fused at the identical site of said antibody light chain

<sup>&</sup>lt;sup>2</sup> The Copycat Biocon IP include PCT/IB2013/001155 which published as WO/2013/164694 and all related patents and foreign counterparts including, but not limited to, U.S. Patent Nos. 8,815,247; 9,340,617; 9,758,582; 9,809,651; 10,144,934; 10,385,348; 11,028,399; 11,060,097; 12,049,632; and U.S. Patent Application No. 18/746,907.

to the identical ligand-binding extracellular domain of TGFβRII via the identical linker that is described in the '789 Bedi IP. Biocon created Bicara for the express purpose of laundering the stolen technology through a new vehicle.

- 8. Biocon and Bicara executed a conspiracy against Y-Trap through three coordinated and fraudulent actions:
- 9. *First*, Biocon licensed to Bicara the Copycat Biocon IP, which included the EGFR/TGFβ-binding fusion protein that Biocon knew was invented by Drs. Bedi and Ravi, not their falsely named inventors. The act of licensing the Copycat Biocon IP to Bicara was pivotal to the conspiracy, as it allowed Bicara to claim protection under the Copycat Biocon IP and falsely assert intellectual property rights to BCA101, concealing that BCA101 in fact was directly copied from the preceding '789 Bedi IP.
- 10. Second, Biocon brazenly claimed inventorship of the '789 Bedi IP, knowing that it had been filed before Biocon ever learned of it from Dr. Bedi. Biocon publicly asserted that its employees were rightful inventors of the '789 Bedi IP, including as recently as 2022-2024 in representations made to the Indian Patent Office. These false claims were aimed at undermining the legitimacy of the '789 Bedi IP, allowing Bicara to evade scrutiny for not holding a valid license to it. Most importantly, this false claim of inventorship allowed Bicara to perpetuate the false narrative that Biocon employees were the original inventors, providing a veneer of legitimacy for Bicara's rights to BCA101. Although the Indian Patent Office rejected Biocon's false claims in August 2024, the damage had already been done, clearing the path for Bicara's initial public offering ("IPO") in September 2024 valuing the company at over one billion U.S. dollars.

- 11. *Third*, Bicara promoted BCA101—originally described in the '789 Bedi IP— and falsely presented it as its own to investors, partners, the oncology community, and the public despite that it knew or should have known of the falsity of Biocon's claims that its employees conceived of any part of the invention claimed by the '789 Bedi IP. From the outset, Bicara accepted the benefits of and adopted Biocon's false inventorship claims, further misleading stakeholders. By misrepresenting the stolen product as its own, Bicara secured large Series B and C financings, conducted clinical trials on its stolen product, and showcased its results in prestigious oncology conferences, cementing its false narrative of ownership. This scheme allowed Bicara to enrich itself at the expense of Y-Trap.
- 12. Bicara and Biocon profited handsomely from their conspiracy and unfair competition to Y-Trap's detriment. In December 2023, Bicara raised \$165 million in a Series C round, just nine months after closing a similarly large \$108 million Series B. Ex XX (https://www.fiercebiotech.com/biotech/bicara-nets-second-nine-digit-haul-nine-months-raising-165m-series-c). Bicara went on to raise over \$360 million in its IPO in September 2024 with a current market capitalization of over \$1 billion. These earnings are, at least in part, due to Biocon's and Bicara's unfair competition and conspiracy. Because Bicara's valuation and IPO were based primarily, if not entirely, on BCA101, Bicara and its major shareholder Biocon have been unjustly enriched by conspiring to misappropriate the '789 Bedi IP.
- 13. Defendants' coordinated activities have also caused substantial harm to Y-Trap. By falsely claiming inventorship over both the '789 Bedi IP and Copycat Biocon IP, Defendants have hindered Y-Trap's ability to secure crucial funding, form joint ventures, establish partnerships in the biotechnology sector and, ultimately, develop multiple life-saving immunotherapies for cancer. Defendants' actions have caused, and continue to cause,

irrevocable harm to Y-Trap by denying it the benefits of clear and unencumbered intellectual property.

### **NATURE OF THE ACTION**

14. Defendants Biocon and Bicara have committed unlawful acts at the expense of Y-Trap. Y-Trap therefore brings this action against Biocon and Bicara for a claim under 35 U.S.C. § 256 for correction of inventorship of the Copycat Biocon IP, unfair competition under Massachusetts M.G.L. CH. 93A, civil conspiracy, and unjust enrichment.

### **PARTIES**

- 15. Y-Trap, Inc. is incorporated in the State of Delaware with its principal place of business located at 1 Tower Place, Suite 800, South San Francisco, CA 94080.
- 16. Upon information and belief, Bicara Therapeutics, Inc. is incorporated in the State of Delaware with its principal place of business located at 116 Huntington Avenue, Suite 703, Boston, MA 02116.
- 17. Upon information and belief, Biocon Ltd. is incorporated in India with its principal place of business located at 20th KM Hosur Road, Electronics City, Bengaluru 560100 Karnataka India.

# **JURISDICTION AND VENUE**

- 18. This Court has subject matter jurisdiction because Count I presents a federal question under 28 U.S.C. §§ 1331, 1338, and 35 U.S.C. § 256. Y-Trap seeks to correct inventorship of patents of the Copycat Biocon IP, naming Drs. Bedi and Ravi as the sole proper inventors (Count I).
- 19. This Court has supplemental jurisdiction over Y-Trap's state law claims for unfair competition (Counts II and III), civil conspiracy (Count IV), and unjust enrichment (Counts V

and VI) because these state law claims (Counts II–VI) arise from a common nucleus of operative fact as the federal law claim (Count I).

- 20. This Court has personal jurisdiction over Defendant Bicara because it has its principal place of business in this District and conducts extensive, continuous, and systematic business activities in this District, which are directly related to the subject matter of this action. Upon information and belief, by way of example, Defendant Bicara's activities in this District include developing the "bifunctional antibodies" which are related to the subject matter of this action. *See* https://www.bicara.com/about/.
- 21. This Court has personal jurisdiction over Defendant Biocon based on acts it committed within the Commonwealth of Massachusetts, including within this District, that have given rise to this suit and/or have established at least minimum contacts with the Commonwealth of Massachusetts and this District such that it should reasonably and fairly anticipate being brought into court in this District and that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice. For example, Defendant Biocon transferred to Defendant Bicara contracts related to developing BCA101 as well as a license to Biocon's patents claiming fusion proteins, including BCA101.

https://www.sec.gov/Archives/edgar/data/2023658/000119312524205393/d821336ds1.htm at 126. Further, Defendant Biocon Ltd. operates a wholly-owned subsidiary in the District of Massachusetts, Biocon Biologics, Inc. Upon information and belief, Biocon Biologics's activities in this District include manufacturing for Bicara the "bifunctional antibodies" which are related to the subject matter of this action. *See* https://www.bicara.com/about/. Thus, Defendant Biocon has unfairly competed with Y-Trap by encouraging Defendant Bicara,

headquartered in this District, to research, develop, and manufacture BCA101, and taking required steps leading to the filing of an Investigational New Drug (IND) and clinical trials.

- 22. Additionally, and/or alternatively, this Court has personal jurisdiction over Defendant Biocon under Federal Rule of Civil Procedure 4(k)(2). This action arises from actions of foreign Defendant Biocon directed toward the United States, including its tortious conduct direct at and contacts with the Commonwealth of Massachusetts, as described herein.
- 23. Moreover, Defendant Biocon has additional contacts with the United States. For example, Biocon is the assignee of several United States patents related to the technology at issue which it has exclusively licensed to Bicara Therapeutics, Inc. (a Massachusetts company) to enable to development and commercialization of BCA101 in this District. As Biocon has purposefully availed itself of the benefits of the United States, including this District, the exercise of jurisdiction over Defendant Biocon would not offend traditional notions of fair play and substantial justice.
- 24. Venue is proper in this judicial district under 28 U.S.C. § 1391(b). Each Defendant either has its principal place of business in this District (Defendant Bicara Therapeutics, Inc.) or has a substantial presence in this District (Defendant Biocon Ltd.). Further, a substantial part of the events or omissions giving rise to Y-Trap's claims occurred in this District and a substantial part of the property that is the subject of this suit is located in this District. For example, upon information and belief, Biocon Ltd. regularly and systematically communicated with Bicara in connection with the research, development, and testing of BCA101 and intellectual property protection related thereto. Upon information and belief, the actions Biocon, Bicara, took to encumber the '789 Bedi IP and obtain the Copycat Biocon IP, which form the basis of this action, were for the benefit of Bicara, which has its principal place of

business in this District. Further, upon information and belief, the majority of relevant witnesses and documents reside in the United States, including in this District, where all Defendants maintain a significant presence.

### **BACKGROUND**

### A. Inventions made at JHU by Dr. Bedi and Dr. Ravi.

- 25. Drs. Bedi and Ravi were both full-time faculty members at JHU, pursuing an NIH-sponsored research program in the Departments of Oncology and Otolaryngology Head and Neck Surgery in the Division of Head and Neck Cancer Research. In the course of their NIH-sponsored research, they conceived of several revolutionary cancer immunotherapies.
- 26. Between 2010 and 2011, Dr. Bedi and Dr. Ravi conceived of inventions that encompass novel fusion proteins comprising a targeting polypeptide (e.g., antibody targeting a tumor cell or tumor-infiltrating immune cell) fused to an immunomodulatory polypeptide (e.g., an extracellular domain of a receptor that binds and disables an immunosuppressive cytokine). As relevant here, the invention specifically includes fusion proteins comprising a targeting moiety that binds epidermal growth factor receptor (EGFR) fused to an immunomodulatory moiety that is a specific ligand-binding sequence of the extracellular domain of TGFβRII, via a specific flexible linker. Accordingly, these fusion proteins, invented by Drs. Bedi and Ravi, bind and disable EGFR and simultaneously sequester and disable TGF-β in the localized microenvironment of EGFR-expressing tumor cells. This enables the fusion protein to induce innate and adaptive antitumor immunity by counteracting TGFβ-induced immune tolerance. JHU filed an international patent application in March 2011 covering these inventions (PCT/US2011/027317), claiming priority to U.S. provisional patent application 61/311,255 (March 5, 2010) and U.S. provisional patent application 61/435,671 (January 24, 2011). As explained above, these applications are part of the '789 Bedi IP.

### B. Interaction of Mazumdar-Shaw and Drs. Bedi and Ravi through IATRICa.

- 27. Prior to the invention of the subject matter disclosed in the '789 Bedi IP, Drs. Bedi and Ravi had previously co-invented an unrelated technology in 2006-2008 with Dr. Shulin Li of Louisiana State University ("LSU") (the "WO '871 family"). In 2008, the WO '871 family, described further below at ¶¶ 59–60, was exclusively licensed by JHU/LSU to a new U.S. company (IATRICa, Inc.) founded by the inventors Drs. Bedi and Ravi (the "2008 Agreement"). In 2008, Biocon became the largest investor in IATRICa, and Biocon chairperson Mazumdar-Shaw became a member of IATRICa's Board of Directors.
- 28. No aspect of the 2008 JHU/IATRICa Agreement gave Biocon or IATRICa any rights to the '789 Bedi IP.
  - C. Bedi makes confidential disclosures to Mazumdar-Shaw and Biocon, after filing '789 Bedi IP patent applications.
- 29. On March 5, 2010, Dr. Bedi filed U.S. provisional patent application 61/311,255 ("JHU's 2010 Provisional Application"), the first filing of the '789 Bedi IP. This provisional application describes, *inter alia*, fusion proteins comprising a targeting moiety that binds EGFR fused to an immunomodulatory moiety comprising a ligand-binding sequence of the extracellular domain of TGFβRII. In particular, the application specifically describes a fusion protein comprising a specific EGFR antibody (cetuximab), wherein the C-terminus of its light chain is fused to a specific ligand-binding sequence of the TGFβRII extracellular domain via a specific flexible linker. Furthermore, the provisional application provides the exact sequence of such a fusion protein.
- 30. On June 23, 2010, following filing of this provisional application, Dr. Bedi confidentially disclosed material regarding the inventions encompassed in the '789 Bedi IP to Mazumdar-Shaw in her capacity as a Board member of IATRICa as a potential new licensing

opportunity for IATRICa. Dr. Bedi's confidential disclosure included the EGFR/TGFβ-binding fusion proteins described above. This was the first instance wherein any employee of Biocon learned of this invention. Mazumdar-Shaw then requested that Dr. Bedi disclose confidential information pertaining to this invention to Biocon scientists, including Dr. Harish Iyer, Biocon's head of research and development at the time, to evaluate its suitability as a possible new licensing opportunity. Dr. Bedi met Dr. Iyer on July 1, 2010, and confidentially disclosed the information in JHU's 2010 Provisional Application. At the time of this disclosure, JHU's 2010 Provisional Application had not yet published, meaning the information provided by Dr. Bedi to Biocon, including Dr. Iyer, was not publicly available and was therefore confidential.

- 31. On January 24, 2011, Drs. Bedi and Ravi filed a second provisional application disclosing additional fusion proteins and their corresponding sequences, U.S. Prov. App. No. 61/435,671. Biocon had no knowledge of these additional claimed fusion proteins until Dr. Bedi made a second confidential disclosure to Biocon employees in February 2011, after the second provisional had been filed. At the time of this disclosure, JHU's 2011 Provisional Application had not yet published, meaning the information provided by Dr. Bedi to Biocon was not publicly available and was therefore confidential.
- 32. In March 2011, JHU filed an international patent application PCT/US2011/027317, claiming priority to U.S. provisional patent application 61/311,255 and U.S. provisional patent application 61/435,671, with inventors Dr. Bedi and Dr. Ravi.
- 33. All information disclosed by Dr. Bedi to Biocon's representatives concerning the '789 Bedi IP, including EGFR/TGF-β-binding fusion proteins, were subject to active CDAs executed between JHU and IATRICa and between Biocon and IATRICa effective March 2007. Therefore, Biocon and its representatives understood that all such information was confidential,

that Drs. Bedi and Ravi were the inventors of the technology, and that the disclosure was solely to evaluate a potential licensing opportunity for IATRICa.

34. In summary, no Biocon scientist was aware of any embodiment of the '789 Bedi IP until *after* Drs. Bedi and Ravi had already filed the respective patent applications. As such, no Biocon scientist could have made any inventive contributions to said patent applications.

# D. Biocon accepts Drs. Bedi and Ravi were the proper inventors of the '789 Bedi IP assigned to JHU.

- 35. At various points following Dr. Bedi's confidential disclosures to Biocon, Biocon acknowledged and accepted that the '789 Bedi IP was JHU intellectual property.
- 36. In an email from Dr. Iyer to Dr. Bedi and others on December 29, 2010, Dr. Iyer acknowledged that Dr. Bedi had filed a provisional application in March 2010, and that Dr. Bedi would file a full PCT before March 2011. As head of R&D, Dr. Iyer knew that no Biocon employees were inventors on these applications and made no such claim.
- 37. In a February 2011 email to Biocon scientists (Kedarnath Sastry and Nagaraj Govindappa), Dr. Bedi reiterated that the confidential attached fusion proteins (including an EGFR/TGF-β-binding fusion protein) were JHU intellectual property: "As we had discussed, the sequences are IP of Johns Hopkins University and cannot be disclosed without a confidentiality agreement." Govindappa and Sastry's responses to this email raise no objections to Dr. Bedi's statements. Dr Bedi's email was a confidential disclosure of fusion proteins from the '789 Bedi IP that he had already invented, and filed in patent applications that were assigned to JHU. Because the material in this email was disclosed to the Biocon scientists under CDA after the invention had already been completed and filed, neither Govindappa, Sastry, nor any other Biocon scientists have any legitimate claim to be inventors. And, in responding to this email, neither of these Biocon scientists made any claim of inventorship.

38. Furthermore, Biocon's understanding that the '789 Bedi IP belongs to JHU (and that Biocon scientists were not inventors) is made evident by Mazumdar-Shaw's attempts to secure a license/sublicense to the WO '789 application from JHU (through IATRICa). Between January and April 2012, Mazumdar-Shaw repeatedly pressured Dr. Bedi to obtain a license to the '789 Bedi IP from JHU to IATRICa, and a sub-license of three molecules encompassed by the '789 Bedi IP from IATRICa to Biocon. In these communications, Mazumdar-Shaw agreed that the '789 Bedi IP is JHU intellectual property (with no claim of Biocon scientists' involvement as inventors), and that the encompassed inventions were a new invention that she wanted to license from JHU.

### BIOCON COPIED THE '789 BEDI IP AND FALSELY CLAIMED IT AS ITS OWN

39. Starting in April 2012, Biocon changed course and began a campaign to sully the '789 Bedi IP and/or usurp the '789 Bedi IP as its own, including by filing its own copy-cat intellectual property, the Copycat Biocon IP.

#### A. Biocon Filed Copy-Cat Intellectual Property

40. On April 30, 2012, Biocon filed a provisional patent application (1689/CHE/2012) of its own, claiming the same subject matter to the '789 Bedi IP. This nearly identical patent application (the first filing of the Copycat Biocon IP – WO 2013/164694 and family members) falsely states on its face that Biocon scientists—not Drs. Bedi and Ravi—are the inventors of this revolutionary technology. The three inventors listed on the Copycat Biocon IP are Nagaraj Govindappa, Kedarnath Sastry, and Melina Soares. Govindappa, Sastry, and Soares are the same Biocon employees to whom Dr. Bedi confidentially disclosed the fusion proteins of his invention, as claimed in the '789 Bedi IP, and who had no knowledge of these fusion proteins before Dr. Bedi's disclosure. Because Dr. Bedi's disclosures to these scientists occurred *after* his patent application filings, the Biocon scientists knew they were not the

inventors of the technology. Yet, Govindappa, Sastry, and Soares audaciously claimed these very same fusion proteins as their own.

- 41. The Copycat Biocon IP describes, *inter alia*, the same EGFR/TGFβ-binding fusion protein described in the first provisional of the '789 Bedi IP (from March 2010). This fusion protein comprises the *identical* anti-EGFR antibody (cetuximab) fused to the *identical* extracellular domain sequence of TGFβRII at the *identical* site (C terminus of the antibody light chain), via the *identical* linker. This *molecule* is the subject of, *inter alia*, the issued U.S. Patent No. 8,815,247 (the "'247 patent") in the Copycat Biocon IP.
- 42. The heavy chain of the aforementioned molecule in the Copycat Biocon IP is the cetuximab heavy chain and is exactly described, amino-acid-for-amino-acid, in the March 2010 provisional, with the insignificant deletion of a single amino acid (lysine) at its C-terminus. This trivial single amino acid deletion was, in any case, already well-known in the art for any antibody, and as such, does not constitute an inventive contribution by Biocon scientists.
- 43. In sum, the three Biocon scientists falsely claimed to invent the very same invention that Dr. Bedi had invented and confidentially disclosed to the same scientists more than one year earlier.
- 44. Thus, the inventorship listed for the Copycat Biocon IP is incorrect. In fact, the true and sole inventor of the '247 patent is Dr. Bedi, and, and more generally, Dr. Bedi or Drs. Ravi and Bedi are the inventors of all patents in the Copycat Biocon IP.

### B. Biocon's Failed Inventorship Allegations Against the '789 Bedi IP

45. Upon information and belief, in 2013, in a letter to JHU and in a books and records demand to IATRICa, Biocon alleged that Biocon scientists should be named co-inventors of the '789 Bedi IP. Upon further information and belief, Biocon did not provide any credible support or basis for this assertion.

- 46. Upon information and belief, Biocon made these false claims in an attempt to coerce a license or sublicense to the '789 Bedi IP. Once unsuccessful, Biocon appeared to abandon its efforts to secure a license to the '789 Bedi IP and appeared to cease its false inventorship claims on the same.
- 47. As far as Dr. Bedi (and later, Y-Trap) knew, Biocon efforts to claim inventorship over the Bedi IP ended in 2014, as they were aware of no further claims by Biocon, after Biocon's claims of inventorship were evaluated and rebuffed. And, upon information and belief, it appeared Biocon that had ceased any public statements or activity with regard to its baseless and unsubstantiated inventorship claims or development efforts of fusion proteins from the '789 Bedi IP, including EGFR/TGF-β binding fusion proteins.

# C. Biocon Lay In Wait For Years While Y-Trap Licensed and Developed the '789 Bedi IP

- 48. In September 2015, Dr. Bedi and Dr. Ravi cofounded Y-Trap to develop products from the '789 Bedi IP. Dr. Bedi serves as the Chief Scientific Officer of Y-Trap. In 2016, Y-Trap procured an exclusive license from JHU to this intellectual property. Y-Trap initiated work to develop multiple bifunctional fusion proteins of the '789 Bedi IP, including but not limited to EGFR/TGFβ-binding fusion proteins, PDL1/TGFβ-binding fusion proteins, and PD1/VEGF-binding fusion proteins.
- 49. In September 2016, the USPTO granted claims from certain patent applications in the '789 Bedi IP directed towards a targeting moiety fused with an immunomodulatory moiety, wherein: (a) the targeting moiety specifically binds Epidermal Growth Factor Receptor (EGFR); and (b) the immunomodulatory moiety comprises an amino acid sequence of the extracellular domain of Transforming growth factor-beta receptor II (TGF-βRII) (U.S. Patent No. 9,441,044).

Upon information and belief, Biocon made no efforts to approach the USPTO to challenge inventorship of this granted patent.

50. Upon information and belief, Biocon made no public announcements until March 2021 about its efforts to develop an EGFR/TGFβ-binding fusion protein embodied by the '789 Bedi IP. This, coupled with Biocon seemingly ceasing its efforts to claim inventorship in 2014, led Y-Trap to reasonably believe that Biocon stopped its efforts to interfere with the '789 Bedi IP and/or to compete with Y-Trap's licensing and development efforts for its fusion proteins derived from the '789 Bedi IP. However, unbeknownst to Y-Trap, Biocon, and eventually its newly formed subsidiary and licensee, Bicara, were surreptitiously developing a fusion protein blatantly copied from the '789 Bedi IP. Biocon secretly conspired with its U.S. subsidiary to spin out Bicara to usurp the product claimed in the '789 Bedi IP and to monetize it at the expense of Y-Trap. Together, Defendants were taking steps to lay the foundation for what would become a billion-dollar business, as explained below.

### BIOCON AND BICARA CONSPIRE TO USURP AND MONETIZE THEIR STOLEN IP

51. Biocon and Bicara executed a conspiracy against Y-Trap to usurp and monetize the '789 Bedi IP, which relied upon the following three coordinated and fraudulent actions.

# A. Biocon licenses its Copycat Biocon IP to Bicara, a subsidiary it launched to monetize BCA101

52. In March 2021, Biocon publicly launched Bicara by providing \$40 million in seed money, issuing a license to the Copycat Biocon IP, and installing Mazumdar-Shaw's niece, Claire Mazumdar, as Bicara's CEO. Bicara launched to develop and commercialize BCA101 (ficerafusp alfa), a molecule blatantly copied verbatim from the '789 Bedi IP. See <a href="https://www.fiercebiotech.com/biotech/bicara-debuts-40m-from-biocon-to-bankroll-bifunctional-antibodies">https://www.fiercebiotech.com/biotech/bicara-debuts-40m-from-biocon-to-bankroll-bifunctional-antibodies</a>. As Bicara describes, "Ficerafusp alfa is a bifunctional antibody that combines two

clinically validated targets, an epidermal growth factor receptor (EGFR) directed monoclonal antibody with a domain that binds to human transforming growth factor beta (TGF-β). https://ir.bicara.com/news-releases/news-release-details/bicara-therapeutics-announces-closing-362-million-initial-public.

- 53. More specifically, BCA101 comprises the *identical* anti-EGFR antibody (cetuximab) fused to the *identical* extracellular domain sequence of TGFβRII at the *identical* site (C terminus of the antibody light chain), via the *identical* linker ((GGGGS)3) as is described in the '789 Bedi IP, including as early as in Drs. Bedi's and Ravi's first provisional application in March 2010. BCA101 comprises a heavy chain and a light chain. The sequence of the light chain fusion protein is exactly described, amino-acid-for-amino-acid in the March 2010 provisional of the '789 Bedi IP. The heavy chain of BCA101 comprises an antigen-binding region that is identical to cetuximab and is exactly described, amino-acid-for-amino-acid, in the March 2010 provisional. *See* Ex. A.
- 54. Importantly, on information and belief, Biocon provided to Bicara a license to the Copycat Biocon IP, which includes coverage of BCA101. The act of licensing the Copycat Biocon IP to Bicara was pivotal to the conspiracy, as it enabled Bicara to claim protection from the '247 patent, and as such, falsely assert intellectual property rights to BCA101. This enabled Bicara to mask the truth that BCA101 in fact was directly copied from the preceding '789 Bedi IP to which they had no license.

#### B. Biocon Makes False Inventorship Claims Over the '789 Bedi IP

55. Unbeknownst to Dr. Bedi (and prior to Y-Trap's incorporation), Biocon filed a pre-grant opposition in the Indian Patent Office to Patent Application 8417/CHENP/2012 (a portion of the '789 Bedi IP) on the basis of incorrect inventorship. No action was taken by the Indian Patent Office following Biocon's initial 2014 filing.

- 56. In February 2022, Biocon filed a Representation for Opposition at the Indian Patent Office, renewing its false inventorship claims by urging the Indian Patent Office to act on its 2014 filing. After Biocon's February 2022 action, Dr. Bedi, JHU, and Y-Trap were first made aware of Biocon's opposition, when they received notice from the Indian Patent Office.
- 57. Biocon states in their February 2022 letter to the Indian Patent Office: "We also do not find, in the available documents in the Patent Office website, any Notice under Rule 55 (3) issued by the Patent Office requesting the applicant to file Reply Statement. Neither have we received a copy of the same." Therefore, neither Biocon nor the Indian Patent Office informed the applicant (JHU) of Biocon's 2014 opposition filing until February 2022.
- 58. The Opposition presented, for the first time, Biocon's basis for its inventorship claim, including Biocon's purported lab notebook pages and other evidence, and detailed argument outlining the alleged significance of the submitted information. Biocon falsely asserted that it has an ownership interest in the '789 Bedi IP on the basis of supposed contributions by its employee, Nagaraj Govindappa. However, all of Biocon's purported evidence and related argument relied on a deceptive attempt to claim an inventive contribution to the '789 Bedi IP on the basis of completely unrelated IATRICa/Biocon co-development work, which pertained exclusively to a wholly different technology described in an unrelated patent portfolio, described below.
- 59. The unrelated technology was developed between 2006 and 2008, by Dr. Bedi and Dr. Ravi at JHU, in collaboration with Dr. Shulin Li at LSU. Drs. Bedi, Ravi, and Li invented protein/nucleic acid hybrid molecules comprising immunostimulatory nucleic acid sequences (double-stranded DNA or RNA) ("INAS") conjugated to targeting polypeptides (e.g., antibodies). The inventors filed two PCT applications describing polypeptide INAS

immunoconjugate technology (WO 2007/089871 and WO 2009/018500) (together referred to herein as "INAS Bedi IP").

- 60. In 2008, IATRICa procured an exclusive license to the INAS Bedi IP from JHU, and entered into a Development and License Agreement ("IATRICa/Biocon Agreement") to codevelop, and sublicense to Biocon, three polypeptide: INAS immunoconjugate products specifically from this invention. The co-development work performed by Biocon and IATRICa on the licensed INAS Bedi IP had nothing to do with the invention of the '789 Bedi IP.
- 61. Biocon knew its scientists were not inventors of the '789 Bedi IP. Nonetheless, between February 2022 and August 2024, Biocon knowingly made a number of false representations in an attempt to substantiate their claims of inventorship.
- 62. Indeed, in August 2024, the Indian Patent Office ruled that Biocon scientists had no inventive contribution to the '789 Bedi IP, rejected, Biocon's opposition, and granted the applicant (JHU) the requested patent affirming Drs. Bedi and Ravi as its sole inventors.
- 63. Biocon knew their claims of inventorship to be false, as evidenced at least by the written communications between Dr. Bedi and Biocon employees, as explained above. These false claims were aimed at undermining the legitimacy of the '789 Bedi IP, allowing Bicara to evade scrutiny for not holding a valid license to it. Most importantly, this false claim of inventorship enabled Bicara to perpetuate the narrative that Biocon was the original inventor, providing a veneer of legitimacy for Bicara's rights to BCA101. Although the Indian Patent Office rejected Biocon's false claims in August 2024, the damage had already been done, clearing the path for Bicara's IPO in September 2024 and a market capitalization above \$1 billion. Furthermore, Biocon's extensive false statements malignly interfered with Y-Trap's

ability to develop any products from the '789 Bedi IP, by casting doubt over the proper inventorship and ownership of this intellectual property.

# C. Bicara Falsely Represents BCA101 as its Own, Claiming to Have All Rights and Licenses

- 64. As of its inception, Bicara knew or should have known of the falsity of Biocon's claims that its employees conceived of any part of the invention claimed by the '789 Bedi IP. Bicara falsely represented BCA101, which is disclosed by the '789 Bedi IP, *see* Ex. A, as its own to investors, partners, the oncology community, and the public. As such, Bicara, too, accepted the benefits of and adopted Biocon's false inventorship claims and made its own similar false claims.
- 65. In March 2021, following Bicara's public announcement of BCA101, a spokesperson for Bicara averred that "its molecules were developed in-house and Bicara owns all rights and licenses." Ex. B (https://www.biospace.com/biocon-launches-bifunctional-antibody-io-subsidiary-bicara-with-40-million). Given that BCA101 is copied from the '789 Bedi IP, was developed out of confidential disclosures from Dr. Bedi to Biocon, and is covered by issued patents from the '789 Bedi IP family, these claims are clearly false.
- 66. Bicara made further false and misleading public statements regarding its purported development of EGFR/TGFβ-binding fusion proteins, including in its IPO S-1 Statement. For example, Bicara stated:
  - "We have built a platform designed to facilitate the development of bifunctional therapies that precisely target the tumor and deliver a tumor-modulating payload to the tumor site . . . . This approach was deployed in the development of ficerafusp alfa, where we believe the bifunctional design can improve upon the therapeutic profile of immunotherapies . . . ."

https://www.sec.gov/Archives/edgar/data/2023658/000119312524205393/d82133 6ds1.htm ("S-1 Statement") at 1-2, 103 (August 22, 2024).

Bicara repeated these statements in registration statements dated September 2, 2024, September 6, 2024, and September 11, 2024. These statements are also contrary to the fact that BCA101 is encompassed by and copied from the '789 Bedi IP.

67. By falsely representing the stolen product as its own, Bicara was able to solicit large private and public financings and use the illegitimately procured funds to conduct clinical trials with their stolen product and widely circulate their results in prestigious oncology conferences and other public forums. This cemented their false public narrative that Bicara was the rightful owner of this intellectual property, thereby enabling Bicara to cloak its stolen IP with this veneer of ill-gotten credibility that it ultimately exploited to enrich itself at the expense of Y-Trap

### D. Defendants Have Significantly Profited From Their Conspiracy

68. Led by Mazumdar, Bicara has raised hundreds of millions of dollars, which, upon information and belief, occurred on the sole basis of the molecule invented by Dr. Bedi and Dr. Ravi. In December 2023, Bicara raised \$165 million in a Series C, nine months after closing a similarly large \$108 million Series B round. https://www.fiercebiotech.com/biotech/bicara-nets-second-nine-digit-haul-nine-months-raising-165m-series-c. Recently, Bicara raised \$362 million in its IPO. https://finance.yahoo.com/news/bicara-therapeutics-closes-362m-ipo-131350103.html. As of October 21, 2024, Bicara's market capitalization was calculated at about \$1.2 billion. https://finance.yahoo.com/quote/BCAX/ (last visited October 21, 2024). As evidenced by Bicara's S-1, BCA101 is the primary asset in Bicara's pipeline (and Bicara's only clinical stage asset), and as such, their valuation is primarily, if not entirely, based on this molecule invented by Drs. Bedi and Ravi. Indeed, Bicara stated, "Our business is highly

dependent on the success of ficerafusp alfa. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize ficerafusp alfa, or if we experience delays in doing so, our business will be materially harmed." S-1 Statement at 6 (September 11, 2024). If BCA101 gains regulatory approval, Defendants stand to further unjustly enrich themselves with billions of dollars in prospective sales.

69. In addition, Bicara may develop additional assets disclosed in the '789 Bedi IP. For example, Bicara's S-1 Statement references BCA300, BCA400, and BCA600, which are likely also derived from the Copycat Biocon IP copied from the '789 Bedi IP.

### E. Bicara, Originally a Biocon Subsidiary, Remains Intertwined with Biocon

- 70. Biocon and Bicara share a close corporate relationship, and each serve to benefit from the unfair and deceptive acts committed by the other in connection with the '789 Bedi IP.
- 71. Biocon launched Bicara with a \$40 million investment to advance its bifunctional antibodies targeting both tumors and the immune system in cancer patients. Ex. B.
- 72. Upon information and belief, Bicara was incorporated as a wholly-owned subsidiary of Biocon in late 2018.
- 73. On October 1, 2019, Bicara and Biocon entered into a Contract Transfer and License Agreement, whereby the parties agreed that Biocon would grant Bicara a license "to make, use, sell, offer to sell, import, and otherwise exploit certain fusion protein products of which ficerafusp alfa was the most advanced program."

https://www.sec.gov/Archives/edgar/data/2023658/000119312524205393/d821336ds1.htm. Bicara paid Biocon INR 550 million as consideration for the license grant. *Id*.

74. Upon information and belief, Bicara was spun out from Biocon in early 2021. Biocon invested forty million dollars in Bicara in exchange for forty million shares of Series Seed Preferred Stock. *Id.* 

75. In a Q2 2024 investor presentation, Biocon reported that it controlled the operations and the Board of Directors of Bicara until at least Q4 2021. However, upon information and belief, the leadership, operations, and financial interests of Biocon and Bicara remain, and will continue to remain, intertwined.

Biocon's and Bicara's leadership overlap substantially. Biocon's Aug. 2024

76.

- Registration Statement discloses that Mazumdar-Shaw, the Chairperson at Biocon, is an investor in Bicara and sits on Bicara's Board of Directors.

  https://www.sec.gov/Archives/edgar/data/2023658/000119312524205393/d821336ds1.htm at 150. Further, Bicara's Chief Executive Officer, Dr. Claire Mazumdar, is the niece of Mazumdar-Shaw. Further, Harvard Medical School professor Vijay Kuchroo served on Bicara's Board of Directors until September 2024, and on Biocon's Board of Directors from 2015 to present. *Id.* at 152; https://www.bioconbiologics.com/about-us/board-of-directors/vijay-kuchroo-biocon/.
- 77. Biocon has provided Bicara with financial support. For example, Bicara's Aug. 2024 Registration Statement discloses that Biocon provided \$10 million to Bicara pursuant to an unsecured loan agreement. *Id.* at F-16.
- 78. Upon information and belief, due to Biocon's ownership interest in Bicara, Biocon has and will continue to benefit from Bicara's success. In an August 2024 SEC filing, Bicara disclosed that "Biocon Limited and its affiliates ("Biocon") with which the Company conducts business, *is the Company's largest shareholder*." *See id.* (emphasis added).

  According to Bicara's Aug. 2024 Registration Statement, Biocon currently holds 1,070,000 shares of common stock and 81,790,144 shares of Series Seed Preferred Stock. *Id.*
- 79. Upon information and belief, due to Bicara's contractual obligations to Biocon subsidiaries, Biocon has and will continue to financially benefit from Bicara's success. By way

of example and without limitation, Bicara and Biocon have entered into a number of agreements which, upon information and belief, are related to the research, development, and manufacture of BCA101 or its predicates.

- 80. For example, Bicara entered into a master services agreement with Biocon which, upon information and belief, is for services related to research and development, clinical trials, regulatory interactions, and manufacturing related to BCA101 or its predicates. *Id.* at F-24.
- 81. Bicara entered into a manufacturing agreement with Biocon Biologics Limited ("BBL") which, upon information and belief, is for the manufacture of BCA101 or its predicates. *Id.* at 184. BBL is a wholly owned subsidiary of Biocon. *Id.* Upon information and belief, Biocon Biologics, Inc. carries out the obligations of that Agreement in the United States.
- 82. Bicara entered into a master services agreement with Biofusion Therapeutics Limited ("Biofusion") which, upon information and belief, is for research and development services related to BCA101 or its predicates. *Id.* at 183–84. Biofusion is a wholly owned subsidiary of Biocon. *Id.*
- 83. As a further example, Bicara entered into a manufacturing agreement and a master contract services agreement with Syngene International Limited ("Syngene"). *Id.* at F-24. Upon information and belief, these agreements are related to the manufacture, research, and development of BCA101 or its predicates. *Id.* Syngene is a wholly owned subsidiary of Biocon. *Id.* at F-25.

#### Y-TRAP'S INTEREST IN THE RELEVANT INTELLECTUAL PROPERTY

- A. Y-Trap is the Exclusive Licensee of the '789 Bedi IP and the Inventions Disclosed and/or Claimed Therein
- 84. In September 2015, Y-Trap was co-founded by Dr. Bedi and Dr. Ravi to develop products from the '789 Bedi IP, including bifunctional fusion proteins comprising a targeting antibody fused to a ligand binding sequence of the TGFβ receptor II ectodomain.
- 85. In 2016, Y-Trap procured an exclusive license from JHU to Y-Trap for the '789 Bedi IP, and the invention disclosed and/or claimed therein.
- 86. Y-Trap has a financial interest in and is the rightful, exclusive licensee of the Copycat Biocon IP because: (1) Drs. Bedi and Ravi are the proper and sole inventors of the Copycat Biocon IP, (2) the Copycat Biocon IP claims the same invention as is disclosed in the '789 Bedi IP, and (3) Y-Trap has an exclusive license to the invention disclosed and claimed in the '789 Bedi IP.
- 87. Y-Trap has a further interest because Y-Trap has an interest in the IP invented by Y-Trap's Chief Scientific Officer, Dr. Bedi, being unencumbered and unsullied by Biocon and Bicara.

### B. Defendants Unjustly Enriched Themselves at the Expense of Y-Trap

88. Defendants conspired to rob Y-Trap of the benefits of its rightfully licensed '789 Bedi IP, while reaping the benefits of advancing a product copied from the same '789 Bedi IP. Defendants obtained hundreds of millions of dollars and a \$1 billion valuation by falsely representing a product from Y-Trap's licensed '789 Bedi IP as their own first-in-class product. Y-Trap has irreparably lost the financial and strategic rewards of having the first-in-class EGFR/TGFβ-binding fusion protein, including high valuation IPO unfairly obtained by Bicara. Notably, Bicara willfully proceeded with its IPO even after Y-Trap made it aware in writing of

the facts contained in this complaint, and after Biocon's claims of inventorship over the '789 Bedi IP had been rejected by the Indian Patent Office. Unfortunately, Bicara's choice to proceed with its IPO furthered the irreparable damage to Y-Trap.

89. Besides the unjust enrichment that they usurped from Y-Trap, Defendants' ongoing conspiracy and unfair competition provide Bicara's copied product BCA101 an unhindered path towards future FDA approval, and the ensuing valuable financial, reputational, and strategic benefits, while robbing Y-Trap of the same. For example, being the first to clinically develop the copied EGFR/TGFβ-binding fusion protein additionally gave Bicara an unfair advantage in running a clinical trial combining BCA101 with Keytruda (pembrolizumab), the standard of care in many tumor types including head and neck cancer. This positions Bicara for a pivotal trial leading to FDA approval, which will allow Bicara to accrue potential billions in sales at the expense of Y-Trap.

# C. Defendants Hindered Y-Trap's Efforts to Develop Fusion Proteins From its Large Portfolio of Products From its Rightfully Licensed IP

- 90. Defendants' coordinated activities have also caused substantial harm to Y-Trap. By falsely claiming inventorship over both '789 Bedi IP and Copycat Biocon IP, Defendants have hindered Y-Trap's ability to secure crucial funding, form joint ventures, establish partnerships in the biotechnology sector and, ultimately, develop life-saving immunotherapies for cancer. Defendants' actions have caused, and continue to cause, irrevocable harm to Y-Trap by denying it the benefits of its own clear and unencumbered intellectual property.
- 91. By falsely claiming inventorship over Y-Trap's entire licensed '789 Bedi IP,
  Defendants unfairly hindered Y-Trap's ability to develop many valuable products from this IP
  for the treatment of patients with cancer. Besides EGFR/TGFβ-binding fusion proteins, such valuable fusion proteins whose development have been unjustly hindered by Defendants include

but are not limited to PDL1/TGFβ-binding fusion proteins and PD1/VEGF-binding fusion proteins. This has resulted in loss of precious patent life and allowed other competitors to eclipse Y-Trap and monetize their products, thereby depriving Y-Trap of these benefits. Indeed, Y-Trap's suffered injury in this District, including on the basis of a potential relationship with a major pharmaceutical company with its principal place of business in this District.

- 92. The obstruction of Y-Trap perpetrated by Defendants has irreparably depressed the value of Y-Trap's intellectual property and thus limited Y-Trap's ability to raise capital on both private and public markets to advance its products. By sullying the legitimacy of the entire '789 Bedi IP via knowingly baseless claims of inventorship,
- 93. Biocon stymied Y-Trap from raising large private/public investment to advance its own products from its large portfolio. Likewise, by obtaining the Copycat Biocon IP under false pretenses (i.e., on the back of Dr. Bedi's and Dr. Ravi's intellectual property), Biocon and co-conspirator Bicara disrupted Y-Trap's ability to raise private and public investment in the same market.
- 94. Furthermore, Defendants' conspiracy has relegated Y-Trap to being seen as offering unoriginal technology (despite being its rightful licensee of the '789 Bedi IP and having been founded by its rightful inventors), thus painting Y-Trap in a further unfavorable light, to the significant detriment of its valuation.
- 95. Relatedly, Defendants have brazenly stolen the scientific and professional accolades and reputational benefits that should have solely accrued to Drs. Bedi and Ravi. Furthermore, Defendants' public defamatory statements impugning the legitimacy of Dr. Bedi and Dr. Ravi's inventions have damaged their scientific and professional reputation. As Drs.

Bedi and Ravi are the scientific co-founders of Y-Trap, and Dr. Bedi serves as its Chief Scientific Officer, these actions have also irreparably harmed Y-Trap.

#### D. Continued Risk to Y-Trap If Defendants' Wrongful Actions Are Allowed to Stand

- 96. Y-Trap remains at risk if Defendants' knowingly false misrepresentations in public forums continues, further damaging the value of Y-Trap's intellectual property and obstructing its ability to develop any of its legitimately licensed products from the '789 Bedi IP while Defendants continue to profit from molecules copied therefrom.
- 97. Biocon copied many molecules from the '789 Bedi IP into their Copycat Biocon IP. As such, significant risk exists that Defendants will repeat their playbook of advancing and monetizing such blatantly copied molecules, whether through Bicara or any other entity Biocon may spawn for this nefarious purpose. Defendants may already be developing, or develop in the future, additional pipeline products from the Copycat Biocon IP and employ the same blueprint to continue to unjustly enrich themselves at the expense of Y-Trap.

# COUNT 1: CORRECTION OF INVENTORSHIP FOR THE COPYCAT BIOCON IP PURSUANT TO 35 U.S.C. § 256

- 98. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.
- 99. Dr. Atul Bedi, or Dr. Bedi and Dr. Rajani Ravi, are inventors of inventions claimed by the Copycat Biocon IP, and patents issuing therefrom, for at least all the reasons detailed above.
- 100. Through omission, Drs. Bedi and/or Ravi are not listed as inventors on the face of the issued patents of the Copycat Biocon IP, for example, including the '247 patent, and the inventors currently listed on the face of the issued patents of the Copycat Biocon IP were

improperly listed. The omission occurred without any deceptive intent on the part of Dr. Bedi or Dr. Ravi.

- 101. For at least all the reasons discussed above, Dr. Bedi and/or Dr. Ravi conceived of all the significant features of the inventions claimed by the Copycat Biocon IP and patents issued therefrom, These contributions were more than explanations of well-known concepts and/or the state of the art at the time of invention.
- 102. For at least all the reasons discussed above, Nagaraj Govindappa, Kedarnath Sastry, and Maria Melina Soares did not contribute to the conception of any significant features of the inventions claimed by the Copycat Biocon IP, and patents issued therefrom. Any alleged contribution of Nagaraj Govindappa, Kedarnath Sastry, and Maria Melina Soares to the inventions claimed by the Copycat Biocon IP, and patents issued therefrom were simply well-known concepts and/or the state of the art at the time of invention.
- 103. Thus, Dr. Bedi or Dr. Bedi and Dr. Ravi are the sole inventors of the inventions disclosed and claimed by the Copycat Biocon IP, and the patents issuing therefrom.
- 104. At the time Dr. Bedi and Dr. Ravi conceived of the inventions claimed by the Copycat Biocon IP, Drs. Bedi and Ravi were under an obligation to assign any inventions, which would include those claimed by the Copycat Biocon IP, to JHU.
- 105. Y-Trap is the exclusive licensee of the '789 Bedi IP and all inventions disclosed and claimed therein, including patents claiming fusion proteins comprising a targeting moiety which binds epidermal growth factor receptor (EGFR) fused to an immunomodulatory moiety that is a specific ligand-binding sequence of the extracellular domain of TGFβRII, via a specific flexible linker, which would include the Copycat Biocon IP and patents issuing therefrom

- 106. As the rightful exclusive licensee of the inventions encompassed by the Copycat Biocon IP Y-Trap derives a financial benefit from and thus has a concrete financial interest in the proper inventorship of the Copycat Biocon IP. Y-Trap also has a financial interest as licensees of the '789 Bedi IP, which covers BCA101, and which has been injured by the Copycat Biocon IP.
- 107. Unless Defendants Biocon and Bicara are enjoined from asserting that Nagaraj Govindappa, Kedarnath Sastry, and Maria Melina Soares are the sole inventors of the Copycat Biocon IP, in violation of U.S. federal patent laws, Y-Trap will suffer irreparable injury. Plaintiff has no adequate remedy at law.
- 108. Because Dr. Bedi or Dr. Bedi and Dr. Ravi are the rightful sole inventors of the claimed features of the inventions claimed in the Copycat Biocon IP and the patents issued therefrom, this Court should direct the Commissioner of Patents to add Dr. Bedi or Dr. Bedi and Dr. Ravi to each of the patents issued from the Copycat Biocon IP as joint inventors and remove Nagaraj Govindappa, Kedarnath Sastry, and Maria Melina Soares as listed inventors.

# COUNT II: UNFAIR COMPETITION BY BIOCON PURSUANT TO M.G.L. CH. 93A

- 109. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.
- 110. Y-Trap and Biocon both participate in the pharmaceutical product industry, and in particular, in the business of developing novel therapeutics for cancer therapy.
- 111. Biocon has engaged and continues to engage in an unfair and deceptive method of competition by, for example, repeatedly and baselessly claiming inventorship and ownership of the '789 Bedi IP and the inventions disclosed and claimed therein (which include the Copycat Biocon IP), of which Y-Trap is the exclusive licensee.

- 112. Biocon's unfair and deceptive methods of competition are detailed above, including its false claims of inventorship and ownership that continue at least through 2024.
- 113. Upon information and belief, Biocon engaged in its unfair and deceptive method of competition in order to clear the path for Biocon—and later for Bicara—to take a product to market that, while currently operating in the safe harbor, infringes the '789 Bedi IP, and to prevent Bedi and Y-Trap from bringing to market a competing product.
- 114. Biocon's unfair and deceptive methods of competition have occurred substantially in Massachusetts. By way of example, and without limitation, Biocon's unfair and deceptive acts have been received and acted upon in Massachusetts, where Bicara and Biocon subsidiary, Biocon Biologics, reside, and where the development of BCA-101 continues to take place. Biocon's unfair and deceptive method of competition has benefitted and continues to benefit Bicara in Massachusetts.
- 115. Biocon has engaged in its unfair and deceptive method of competition willfully and knowingly.
- 116. Biocon's activities are causing and will continue to cause severe and irreparable injury to Y-Trap, including in the form of loss and diminution of its competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace, for which there is no adequate remedy at law. Y-Trap is therefore entitled to an injunction restraining and enjoining Biocon and its agents, servants, officers, directors, and employees, and all persons acting thereunder, in concert with, or on its behalf, from making further disparaging and untrue statements about the inventorship and ownership of the '789 Bedi IP or the Copycat Biocon IP.

- 117. Further, by way of example, and without limitation, Bicara's unfair and deceptive acts have harmed Y-Trap in Massachusetts, where research and development related to Y-Trap's own product was planned to occur before Y-Trap's Massachusetts-based partner pulled out of the agreement due to the uncertainty manufactured by Bicara regarding the Bedi IP.
- 118. Biocon's activities have directly and proximately caused significant damages to Y-Trap, including in the form of loss of competitive position in the marketplace, lost opportunity to commercialize its lucrative class of cancer immunotherapy drugs, lost licensing revenue, and other general and specific damages in an amount to be proven at trial.
- 119. Biocon's violation of M.G.L. ch. 93A through its unfair or deceptive acts or trade practices was done willfully and/or knowingly, thereby entitling Y-Trap to enhanced damages and attorneys' fees and costs as permitted by M.G.L. ch. 93A.

## <u>COUNT III:</u> UNFAIR COMPETITION BY BICARA PURSUANT TO M.G.L. CH. 93A

- 120. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.
- 121. Y-Trap and Bicara are both focused on discovering and developing immunotherapy for cancer, specifically bifunctional EGFR/TGF-βRII-binding fusion proteins.
- 122. Bicara has engaged and continues to engage in an unfair and deceptive method of competition at least through Biocon's repeated and baseless claims of inventorship and ownership of the '789 Bedi IP, and the inventions disclosed and claimed therein (which includes the Copycat Biocon IP).
- 123. As of its inception, Bicara knew or should have known of the falsity of Biocon's claims that its employees conceived of any part of the invention claimed by the '789 Bedi IP.

  Bicara has benefited from the lack of competition in bringing BCA101 to market and from

Biocon's encumbrance of the '789 Bedi IP by hindering Y-Trap's ability to compete. Because Bicara has accepted the benefits of Biocon's unfair and deceptive method of competition, and has ratified these actions, it is thus liable for Biocon's unfair and deceptive acts.

- 124. Bicara has engaged and continues to engage in an unfair method of competition by repeatedly and baselessly claiming all rights and licenses, including by endorsing Biocon's false inventorship and ownership claims over of the '789 Bedi IP, and the inventions disclosed and claimed therein (which includes the Copycat Biocon IP), of which Y-Trap is the exclusive licensee. Bicara ratified Biocon's unfair and deceptive acts and perpetuated its own, including through statements claiming to have developed fusion protein technology, which was taken from the '789 Bedi IP.
- 125. Bicara has engaged in its unfair and deceptive method of competition willfully and knowingly.
- 126. Bicara's unfair or deceptive acts or trade practices have occurred substantially in Massachusetts. By way of example and without limitation, Bicara, which resides in Massachusetts, has ratified Biocon's unfair or deceptive acts or trade practices in Massachusetts by accepting in Massachusetts the benefits of Biocon's unfair and deceptive method of competition.
- 127. Bicara's activities are causing and will continue to cause severe and irreparable injury to Y-Trap, including in the form of loss and diminution of its competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace, for which there is no adequate remedy at law. Y-Trap is therefore entitled to an injunction restraining and enjoining Bicara and its agents, servants, officers, directors, and employees, and all persons acting thereunder, in concert with, or on its behalf,

from making further disparaging and untrue statements about the inventorship and ownership of the '789 Bedi IP and the inventions disclosed and claimed therein (which includes the Copycat Biocon IP).

- 128. Bicara's activities have directly and proximately caused significant damages to Y-Trap, including in the form of loss of competitive position in the marketplace, lost opportunity to commercialize its lucrative class of cancer immunotherapy drugs, lost licensing revenue, and other general and specific damages in an amount to be proven at trial.
- 129. Bicara's violation of M.G.L. ch. 93A through its unfair or deceptive acts or trade practices was done willfully and/or knowingly, thereby entitling Y-Trap to enhanced damages and attorneys' fees and costs as permitted by M.G.L. ch. 93A.

# COUNT IV: UNJUST ENRICHMENT BY BICARA

- 130. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.
- 131. Bicara has been, and is continuing to be, unjustly enriched by licensing the Copycat Biocon IP, by receiving the benefit of the false statements made by Biocon related to inventorship and ownership of the '789 Bedi IP, and by falsely representing that Bicara has all rights to the molecule comprising BCA-101, which is part of the inventions disclosed and claimed in the '789 Bedi IP.
- 132. Biocon's actions conferred a benefit on Bicara. By way of example, and without limitation, upon information and belief, Bicara has improperly used its position in the marketplace to raise hundreds of millions of dollars and to reach an IPO with a market capitalization over one billion dollars.

- 133. Bicara received and will receive significant financial and other rewards as a result of the benefit Biocon's statements with regard to inventorship of the '789 Bedi IP, including in its ability to raise hundreds of millions of dollars and to reach an IPO with a market capitalization over one billion dollars.
- 134. Allowing Bicara to retain the benefits under the circumstances from its improper ratification of Biocon's false statements regarding inventorship and ownership of the '789 Bedi IP would be unjust, unwarranted, and inequitable.
- 135. Bicara's activities are causing and will continue to cause severe and irreparable injury to Y-Trap, including in the form of loss and diminution of its competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace, for which there is no adequate remedy at law. Y-Trap is therefore entitled to an injunction restraining and enjoining Bicara and its agents, servants, officers, directors, and employees, and all persons acting there under, in concert with, or on its behalf, from making disparaging and untrue statements about the inventorship of the '789 Bedi IP, representing that Bicara owns all rights to the underlying technology, and holding out the Copycat Biocon IP as being invented by anyone other than Dr. Bedi and/or Dr. Ravi.
- 136. Bicara's activities have directly and proximately caused significant damages to Y-Trap, including in the form of loss of competitive position in the marketplace, lost opportunity to commercialize its lucrative class of cancer immunotherapy drugs, other economic losses, and other general and specific damages in an amount to be proven at trial.

# COUNT V: UNJUST ENRICHMENT BY BIOCON

137. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.

- 138. Biocon has been, and is continuing to be, unjustly enriched by licensing the Copycat Biocon IP to Bicara, by receiving the benefit of the false statements Biocon made related to inventorship and ownership of the '789 Bedi IP, and by falsely representing that Bicara has all rights to the molecule comprising BCA-101, which is part of the inventions disclosed and claimed in the '789 Bedi IP.
- 139. Biocon's actions conferred a benefit on Biocon by allowing it to earn significant return on its investment in Bicara. By way of example, and without limitation, upon information and belief, Bicara has improperly used its position in the marketplace to raise hundreds of millions of dollars and to reach an IPO with a market capitalization over one billion dollars.

  Biocon, as a major investor in Bicara stands to earn significant return on its initial investment.
- 140. Allowing Biocon to retain the benefits under the circumstances from its improper ratification of Biocon's false statements regarding inventorship and ownership of the '789 Bedi IP would be unjust, unwarranted, and inequitable.
- 141. Biocon's activities are causing and will continue to cause severe and irreparable injury to Y-Trap, including in the form of loss and diminution of its competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace, for which there is no adequate remedy at law. Y-Trap is therefore entitled to an injunction restraining and enjoining Biocon and its agents, servants, officers, directors, and employees, and all persons acting there under, in concert with, or on its behalf, from making further disparaging and untrue statements about the inventorship and ownership of the '789 Bedi IP.
- 142. Biocon's activities have directly and proximately caused significant damages to Y-Trap, including in the form of loss of competitive position in the marketplace, lost opportunity

to commercialize its lucrative technology class of cancer immunotherapy drugs, other economic losses, and other general and specific damages in an amount to be proven at trial.

# CIVIL CONSPIRACY TO COMMIT UNFAIR COMPETITION BY BIOCON AND BICARA TOGETHER

- 143. Y-Trap incorporates and realleges the foregoing paragraphs as if fully set forth herein.
- 144. By engaging in the wrongful and unlawful conduct described above, Defendants Biocon and Bicara intentionally and willfully entered into a conspiracy for Defendants' own benefit and in derogation of Y-Trap's interests to unlawfully disrupt Y-Trap's ability to compete in the market.
- 145. Defendants conspired to weaken the '789 Bedi IP and copied the inventions disclosed in the '789 Bedi IP to enable themselves to develop and commercialize technologies competing directly with Y-Trap, and improve their competitive position, and increase their market share in the field.
- 146. Defendants' activities are causing and will continue to cause severe and irreparable injury to Y-Trap, including in the form of loss and diminution of is competitive position in the marketplace, loss of its ability to offer unique products, and lost opportunities to capitalize on its status in the marketplace, for which there is no adequate remedy at law. Y-Trap is therefore entitled to an injunction restraining and enjoining Defendants and their agents, servants, officers, directors, and employees, and all persons acting thereunder, in concert with, or on their behalf, from making further disparaging and untrue statements about the inventorship and ownership of the '789 Bedi IP.
- 147. Defendants' activities have directly and proximately caused significant damages to Y-Trap, including in the form of loss of competitive position in the marketplace, lost

opportunity to commercialize its lucrative class of cancer immunotherapy drugs, other economic losses, and other general and specific damages in an amount to be proven at trial.

### JURY TRIAL DEMAND

148. Y-Trap hereby demands a trial by jury of all issues so triable.

## **PRAYER FOR RELIEF**

Wherefore, Y-Trap prays for judgment as follows:

- A. Compensatory damages (including Y-Trap's lost profits and consequential damages, disgorgement of Defendants ill-gotten profits, unjust enrichment, payment of a reasonable royalty and/or reliance damages) in an amount to be determined at trial, with interest;
- B. Enhanced and punitive damages as permitted by law, including M.G.L. ch.93 § 42B and M.G.L. ch. 93A § 11;
- C. An order under 35 U.S.C. § 256 naming Dr. Bedi or Dr. Bedi and Dr. Ravi as the sole inventors of the Copycat Biocon IP and all patents issued therefrom;
- D. Any and all equitable relief that may be available to Y-Trap, including, without limitation, restitution, disgorgement, the imposition of a constructive trust, and/or specific performance of assignment of BCA-101 and any fusion proteins disclosed in or derived from the '789 Bedi IP;
- E. Injunctive relief under M.G.L. ch. 93 § 42B and M.G.L. ch. 93A § 11;
- F. Costs and reasonable attorneys' fees, as permitted by law; and
- G. Such other and further relief as the Court deems just and reasonable.

Dated: October 22, 2024 Respectfully submitted,

Y-TRAP, INC.

By its attorneys,

By: /s/ Benjamin Stern

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